Experimental Study on Consumer Responses to Nutrition Facts Labels with Various Footnote Formats and Declaration of Amount of Added Sugars

0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) regulates the labeling of food products under the Federal Food, Drug, and Cosmetic Act, as amended by the Nutrition Labeling and Education Act (NLEA) of 1990 (Public Law No. 101–535). NLEA specified that most packaged foods must bear nutrition labeling, including certain nutrients and food components that may be added or deleted by regulation as necessary to assist consumers in maintaining healthy dietary practices. In response to NLEA, when FDA was determining which Nutrition Facts label format to require, the Agency undertook consumer research to evaluate alternatives (Refs. 1 through 3). In 1993, FDA issued rules (codified in 21 CFR part 101) describing the content and format of nutrition labeling, including the mandatory and standardized Nutrition Facts label. When the Agency issued those rules, it considered the diet and health information that was current at that time. Since then, new information has become available, including but not limited to the Dietary Guidelines for Americans, 2010 (Ref. 4) and various Institute of Medicine (IOM) reports that update recommendations for the intake of vitamins, minerals, and macronutrients (Refs. 5 through 11). In addition, research has examined how consumers use the Nutrition Facts label and how consumers respond to specific components of the label such as the percent Daily Value (Refs. 3, 12 through 14). In light of this accumulation of new information, and given the documented rise in the incidence and prevalence of diet-related chronic diseases and health concerns such as diabetes, hypertension, and obesity, the Agency considers it necessary to update information on the Nutrition Facts label to assure that consumers have the information necessary to make healthful dietary choices.

In the Federal Register of November 2, 2007 (72 FR 62149), FDA issued an advance notice of proposed rulemaking (ANPRM) entitled, ‘‘Food Labeling: Revision of Reference Values and Mandatory Nutrients’’ (the 2007 ANPRM), which requested comments on a variety of topics related to a future proposed rule to update the presentation of nutrients and nutrient values on food labels. In response to the 2007 ANPRM, the Agency received many comments that recommended removing the Nutrition Facts label footnote (§ 101.9(d)(9)(i)), and many suggested replacing it with simpler information that can be more readily understood by consumers. These comments and existing research evidence have persuaded the Agency that much of the footnote information—specifically, the table listing that displays Daily Values for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 and 2,500 calorie diets—is not well understood or used by consumers as expected.

On June 26, 2000, the Agency published a notice of availability of a petition received on August 3, 1999 from the Center for Science in the Public Interest (CSPI) that requested the Agency to require the Nutrition Facts label to disclose the quantity of added sugars present in packaged foods and to establish a daily reference value for "added sugars" (Docket No. FDA-1999-P-0158). Subsequent to making that petition available, the Agency received more than 2,700 comments from individuals, industry, academic institutions, advocacy groups, and health care groups. The vast majority of comments were in support of declaring the amount of added sugars on the Nutrition Facts label. The Agency also received comments to the 2007 ANPRM related to the labeling of added sugars; some comments favored such labeling, whereas other comments opposed it.

Based on the information noted above, the Agency has determined that research should be conducted to assess consumer reactions to (1) various statements presented in the Nutrition Facts footnote that explain percent Daily Values and how to use them and (2) declaration of added sugars. The Agency is not aware of any existing consumer research that has examined these particular topics and is interested in using this study to inform future consumer education related to understanding and using Nutrition Facts labels.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

The study is part of the Agency's continuing effort to provide consumers with information to assist them in making informed dietary choices and constructing healthful diets. Results of the study will inform the Agency's understanding about consumers' current perceptions and use of information appearing on the Nutrition Facts label and will inform future education efforts.

Determining whether added sugars are inherently less healthy is not part of the objective of the proposed research. The proposed consumer research does not apply specific definitions of healthful foods, nor does the research equate the presence or the amount of added sugars as necessarily decreasing the healthfulness of a food. The study aims to examine how consumers' evaluations of Nutrition Facts information would change if added sugars declarations appeared on these labels, given their current understanding of the term "added sugars." Different participants will be randomly assigned to evaluate nutrition information for the same foods; in some cases, this nutrition information would include added sugars declarations, and in other cases, it would not. By examining whether consumer evaluations of nutrition information for the same foods change as a result of including added sugars declarations, we can better understand the potential effect of added sugars declarations on consumers' food product perceptions. This information, in turn, can help guide FDA's future education efforts about added sugars and efforts to help consumers understand and use the Nutrition Facts label.

The data collection will include a single experimental study whose overall objective is to examine consumer reactions to two main categories of potential modifications to the

Nutrition Facts label: (1) replacement of the existing information in the footnote area with other statements; and (2) insertion of a separate declaration for added sugars below the declaration for sugars. Appendix A lists the specific footnote statements to be tested, which include a description of percent Daily Value, a succinct statement about daily caloric intake, a general guideline for interpreting percent Daily Values, or a footnote about nutrients whose daily intake should be limited.. The test label formats that declare added sugars are included Appendix B.

The study will include a range of dependent measures to assess the value of each nutrition labeling modification in enabling healthier food choices:

(1) Consumer ability to perform label usage tasks, including identifying and evaluating the levels of vitamin, mineral, and other nutrient content of selected products.
(2) Consumer perceptions about a food product, including nutritional attributes and overall healthfulness.
(3) How footnote messages influence consumer use of other information in the Nutrition Facts label.
(4) Consumer understanding of Nutrition Facts label formats that include a declaration for added sugars in addition to the required nutrients.
(5) Influences of amount of added sugars, when declared, relative to information about calories, sugars or "total sugars," and other nutrients, on consumer ability to identify the more healthful product in a pair of products.
(6) Consumer responses to a label format in terms of its perceived understandability, helpfulness, usefulness, and believability in conveying information for dietary decisions and the product's nutritional attributes.

The proposed data collection is an experimental study that aims to establish causal relationships between test conditions and consumer responses. For an experimental study, the primary concern is that the design has sufficient internal validity to establish one or more of the causal relationships in question and sufficient statistical power to detect differences between conditions. For experiments, convenience samples are commonly used, along with procedures such as random assignment and the use of control groups. Because the proposed study is not a survey that aims to generate population estimates, the need for a nationally representative sample is diminished.

Each of the planned 10,000 participants will be randomly assigned to one of 73 experimental conditions, 28 of which will focus on evaluating footnote modifications (7 footnotes × 2 product categories × 2 nutrition profiles) and 45 of which will focus on evaluating the effects of an added sugars declaration (3 labeling conditions × 3 product categories × 5 nutrition profiles). One reason for the proposed sample size is to allow for assessment of interactions between the experimental factors (e.g., label format × food category × nutrition profile). The ability to detect interactions is essential for addressing a number of the central objectives of the study. For example, testing for interactions will allow us to examine whether the footnote messages improve consumers' ability to use percent daily values to differentiate between products that have different nutrition profiles, i.e., levels of nutrients such as fat, sodium, and vitamins and minerals. Testing

for interactions will also help us examine whether and how consumers' product evaluations change in response to varying nutritional profiles, and whether the change in these responses varies depending on the inclusion of added sugars declarations as well as in response to the amount of added sugars declared. Given that we are conducting multiple statistical tests, we plan to apply statistical corrections to adjust for inflated error rates or false positive findings, and these corrections reduce our statistical power. Another reason for the proposed sample size is to allow for subgroup analyses to assess whether effects of the label modifications may vary by demographic and other key characteristics (e.g., level of education, gender, race/ethnicity, age, and frequency of nutrition label usage).

The study will test whether the following null hypotheses hold:

Hypothesis 1: There is no difference in perceptions about a food's nutritional attributes or overall healthfulness between any of the five footnote message conditions and a control labeling condition with the current footnote.

Hypothesis 2: There is no difference in perceptions about a food's nutritional attributes or overall healthfulness between any of the five footnote message conditions and a control labeling condition with no footnote.

Hypothesis 3: The patterns of responses on the dependent measures do not differ among the five footnote message conditions.

Hypothesis 4: There is no interaction between the footnote message and a product's nutritional profile in how people respond to the dependent measures.

Hypothesis 5: There is no difference in consumer comparisons, comprehension, or perceptions about a food's nutritional attributes or overall healthfulness between label conditions that include a declaration for added sugars and a control label condition with no such declaration.

Hypothesis 6: There is no difference in consumer comparisons, comprehension, or perceptions about a food's nutritional attributes or overall healthfulness between a label condition in which an added sugars declaration is indented below a "Sugars" declaration, and a label condition in which an added sugars declaration is indented below a "Total Sugars" declaration.

Hypothesis 7: The patterns of perceptions about a food's nutritional attributes or overall healthfulness do not differ when the amount of added sugars differs but other nutrients are held constant.

Hypothesis 8: There is no interaction between products' overall nutritional profile and added sugars content in how people respond to the dependent measures.

Results of this study will be used to inform the Agency's understanding about consumers' current perceptions and use of information appearing on the Nutrition Facts label and will inform future education efforts related to the label. The study results will also enhance the Agency's understanding of how consumers perceive various potential modifications to the Nutrition Facts label, such as the declaration of added sugars, perceptions which may in turn affect consumers' dietary choices.

3. Use of Improved Information Technology and Burden Reduction

   The study will use web-based surveys. Web-based surveys not only reduce the burden on respondents, but also minimize possible administration errors and expedite the timeliness of data collection and processing. Compared to face-to-face interviews and mailed surveys, web-based surveys are less intrusive and less costly.

4. Efforts to Identify Duplication and Use of Similar Information

   The proposed experimental study is not duplicative of existing information. The proposed study builds on and updates earlier quantitative research conducted around the time that NLEA was implemented, and augments findings from more recent but primarily exploratory qualitative research conducted by the Agency.

5. Impact on Small Businesses or Other Small Entities

   No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

   This is a one-time data collection. If this information is not collected, FDA will not know how proposed modifications to the Nutrition Facts label may affect consumer comprehension and perceptions. This lack of information would impede FDA's ability to optimize educational activity related to Nutrition Facts label information. The study is part of the Agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets through labeling and/or consumer education.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of May 31, 2012 (77 FR 32120). FDA received 19 written responses containing multiple comments. Many comments outlined detailed technical feedback regarding the design of a draft questionnaire that was associated with a Federal Register notice published on December 29, 2011 (76 FR 81948). That notice was officially withdrawn in a subsequent Federal Register notice published on May 31, 2012 (77 FR 32122) and all documentation associated with the withdrawn notice is considered obsolete. The Agency also received comments related to the declaration of added sugars on the Nutrition Facts label. To the extent that comments about added sugars declarations raised regulatory, policy, and nutrition science issues, the Agency notes that such

comments are not directly related to the proposed consumer research and are therefore not addressed here.

(Comment 1) While a number of comments supported the proposed collection of information, a number of comments also questioned whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility. Among the issues raised with regard to whether the information is necessary for the proper performance of FDA's functions was whether the Agency has sufficient justification to require, or the ability to enforce, added sugars declarations on Nutrition Facts labels. These comments discussed an uncertain relationship between added sugars and chronic health conditions, the current inability of most analytical methods to detect added sugars content in foods, and views on added sugars declarations that the Agency has historically expressed.

(Response 1) The Dietary Guidelines for Americans 2010 (2010 DGA) recommend the reduction in consumption of added sugars which currently comprise 16% of the daily energy intake. The DGA noted that "many foods that contain added sugars often supply calories, but few or no essential nutrients and no dietary fiber." The current Nutrition Facts label does not permit the declaration of added sugars on the label. Section 403(q)(2)(A) of the Federal Food, Drug, and Cosmetic Act provides that the Secretary of Health and Human Services may, by regulation, require other nutrients to be declared in nutrition labeling if the Secretary determines that a nutrient will provide information regarding the nutritional value of a food that will assist consumers in maintaining healthy dietary practices. The Agency proposes to examine added sugars declarations, along with other label modifications, in this information collection. The information gathered will have utility for the Agency as general information about consumers' current perceptions and use of information appearing on the Nutrition Facts label and will inform future education efforts. The study may also inform the Agency about what changes it should consider related to the Nutrition Facts label. The Agency's proposal to conduct consumer research on added sugars declarations does not constitute a proposal for changes in which nutrients must or may be declared on the Nutrition Facts label. Comments concerning regulatory, policy, and nutrition science related to added sugars declarations are outside the scope of this proposed collection of information. If and when the Agency proposes changes to the current format and content of the Nutrition Facts label, the public will be invited to comment on the relevant regulatory, policy, and nutrition science questions. Further, the concerns raised by the comments would not necessarily preclude the Agency from proposing changes to the Nutrition Facts label that may be informed by this study.

(Comment 2) A number of comments offered suggestions about additional consumer research or raised policy or nutrition science matters for consideration. Specifically, one comment recommended that FDA evaluate the effects of labels that show only added sugars and juice sugars, instead of showing total sugars. The same comment also suggested that FDA test consumers' understanding of how much sugar a food contains when amounts are provided in teaspoons as opposed to grams. Two comments urged FDA to set a daily value for sugars, added sugars, or both. One comment urged FDA to evaluate the effect on consumers of distinguishing between whole vs. refined fiber on the

Nutrition Facts label, as recommended by the Institute of Medicine. One comment suggested identifying a disqualifying level of total or added sugars that would make a product ineligible to have a health claim on its packaging because certain foods that are high in sugars may bear health claims and mislead consumers to think a product is healthier than it is. One comment noted that certain juice products may have more added sugars than, but the same or lower level of total sugars as, other juice or dried fruit products. The comment claimed that highlighting added sugars would minimize the health benefits of those products that contain more added sugar but lower total sugar than other juice or fruit products.

(Response 2) These comments are outside of the scope of the proposed collection of information described in the 60-day notice and therefore are not addressed here.

(Comment 3) Multiple comments cited the importance of evaluating consumer responses to potential changes to the Nutrition Facts label and how consumer understanding of the nutritional attributes of packaged foods may be affected by these changes, and therefore supported the proposed study.

(Response 3) The Agency agrees with these comments.

(Comment 4) Multiple comments noted the importance of educating consumers about how to make positive food choices, rather than relying solely on Nutrition Facts labeling as a method of assisting consumers in maintaining healthy dietary practices.

(Response 4) FDA agrees that consumer education is important to help consumers understand how to make healthy dietary choices, and has been conducting and sponsoring a variety of education efforts through its website (e.g., Refs. 15 to 20) and other programs such as the “Spot the Block” campaign (Refs. 19 and 20). The results of the proposed study will provide the Agency additional information to help guide future consumer education about how to use food labels to make healthy dietary choices.

(Comment 5) One comment noted that while Internet-administered questionnaires minimize burden on respondents and possible administration errors, expedite the timeliness of data collection and processing, and are less intrusive and less costly than other modes of questionnaire administration, there are also drawbacks to this mode of survey administration. Two comments noted limitations pertaining to online consumer panels, specifying that because panel-based samples are not representative of the general U.S. population, the results of the study cannot be applied to all U.S. consumers. One comment questioned why the Agency has not elected to restrict the research to respondents who shop for food or who read Nutrition Facts labels. The comment suggested that the study should screen for consumers who have a high probability of seeing Nutrition Facts labels or who actually consume or purchase the types of food products to be included in the proposed study.

(Response 5) The Agency acknowledges the limitations of Internet-administered research and the constraints associated with using samples drawn from online consumer panels.

We note that the study is a controlled experimental study that would employ random assignment and is intended to examine causal relationships between certain label format modifications and respondents' reactions to the modifications. The study is not a survey that aims to generate population estimates of how many consumers would react to different modifications in particular ways. Because the study is not intended to generate population estimates, the Agency disagrees that the limitations of the sample would preclude meaningful conclusions about potential effects of the label format modifications, or that the study should be limited to participants characterized by particular label use or product use habits. In describing the data collected and results of the analysis, FDA will clearly acknowledge that the experimental data do not provide nationally representative population estimates of consumer understanding, behaviors, or perceptions, but nevertheless provide valid and quantitative estimates of differences across experimental conditions.

(Comment 6) Three comments expressed concern about asking respondents to judge the overall healthfulness of the products they view in the study. These comments noted that consumers' definitions of healthfulness may or may not be consistent with FDA's regulatory definition of healthy. Because different consumers are likely to define "healthier" using different criteria, one comment suggested providing a definition of "healthier" to ensure that all respondents are using the same definition. The comment asserted that because respondents may use idiosyncratic bases for responding to such questions, it is unclear how the results can be compared across respondents. The same comment noted similar concerns about asking participants to report their perceptions of how much sugar a product contains, how well they understand the content of a given label, or how likely they would be to include a given product as part of their diet.

(Response 6) The Agency disagrees with these comments. These comments fail to account for the randomized, controlled, experimental design of the proposed research and mischaracterize the primary function of the selected measures in the context of the proposed study. The proposed study is not a cross-sectional survey, but rather an experiment. Relative to cross-sectional surveys, properly designed experiments are better able to determine causal effects attributable to the independent variables, such as the nutrient levels shown on the Nutrition Facts label, which have been systematically varied by the experimenter. As an experiment, the focus is on the differences observed between treatment groups (e.g., those who see labels with format modifications) and control groups (e.g., those who see labels in the current Nutrition Facts format). Because participants will be randomly assigned to experimental conditions that systematically vary in certain respects, idiosyncratic variations, such as individuals' understanding of healthfulness and different ways of judging the relative nutrient content of various foods, are likely to be distributed evenly across conditions. As a result, differences in outcomes that may be observed between conditions would most likely be due to experimental factors as opposed to individual idiosyncrasies.

Thus, the Agency has proposed an experimental method for understanding the causal effects of added sugars declarations on consumer responses to Nutrition Facts labels. The measurement approaches selected for the proposed study are well-established and have

been employed in numerous peer-reviewed scientific publications (see, for example, Refs. 1 to 3, 21 to 30). In studies such as these, participants demonstrate their practical understanding of the nutritional information about selected foods through their completion of selected dietary tasks, such as comparing the healthfulness of different food items or judging how healthful they think a product is. Importantly, research has demonstrated that if consumers perceive that a product is healthful, they may be more likely to purchase or consume more of that food, and may be more likely to view that food as possessing other positive attributes that it may not objectively have (Refs. 31 and 32). Thus, consumer judgments of product healthfulness as well as calorie and nutrient levels will serve as vital indicators of how various Nutrition Facts information and formats may assist consumers in identifying healthful food products and in comparing the calorie and nutrient contents of different food products. In turn, data derived from this research will assist the Agency in determining directions for future research and educational activities.

For the purposes of this study, it is not necessary to provide consumers with a specific definition of "healthier." The study aims to examine what consumers may infer from the Nutrition Facts labels based on their own interpretations, not to examine definitions of "healthy" or "healthier" according to regulatory or scientific perspectives. Evaluating potential effects of added sugars declarations on consumers with a diverse range of nutrition knowledge using a randomized, controlled, experimental study will provide useful information about consumers' current perceptions and use of information appearing on the Nutrition Facts label and will inform future education efforts.

While random assignment is the most robust method for significantly reducing the plausibility of individual difference explanations for observed differences between treatment and control conditions, we also plan to collect measures of individual characteristics that will allow for some statistical control of potential confounders. The measurement of these additional covariates (e.g., how often people eat and purchase the categories of foods included in the study, people's typical label use frequency, demographic characteristics, etc.) will further enhance the study's explanatory power.

(Comment 7) One comment questioned the utility of collecting participants' ratings of a given label's usefulness and helpfulness for making various dietary judgments.

(Response 7) The measures to which this comment refers (e.g., asking respondents to rate on a scale from 1 = "not at all" to 5 = "very" how hard it is to understand the information shown on the label) are indicators of consumers' attitudinal responses toward the label formats. FDA draws a distinction between these types of attitudinal measures and behavioral performance measures (i.e., how well consumers use a label format for completing a specific task, such as judging healthfulness and identifying nutritional characteristics of a product). The Agency has typically considered behavioral performance measures to be more consequential than ratings of label usefulness, understandability, and helpfulness. Nevertheless, the Agency also collects these ratings because it is possible that inferior ratings of usefulness, understandability, and

helpfulness could be indicative of a potential problem with a particular label modification or label format. It is therefore important to collect these kinds of ratings.

(Comment 8) Some comments asserted that including added sugars declarations would detract from consumers' focus on other nutrition information, specifically total calories. Related comments noted that consumers would be confused or misled by added sugars declarations. A few comments proposed that consumer research should focus on exactly how consumers understand the term "added sugars," the particular meanings that consumers attach to various kinds of sugars, and the health effects that consumers associate with added sugars. Two comments asked if FDA plans to explore whether including "added sugar" and "naturally occurring sugar" on the Nutrition Facts label under total sugars would increase consumer understanding of products' nutritional attributes and healthfulness. One comment requested that the Agency establish definitions that differentiate between added sugars and naturally occurring sugars before conducting consumer research. These comments expressed concern that consumer understanding about sugars does not match definitions that might be endorsed by various regulatory or scientific entities. Another comment suggested that the Agency study how information about added sugars in ingredient listings might affect attention to and understanding of information in the Nutrition Facts.

(Response 8) The Agency agrees that the questions raised in these comments would be suitable for future research. The purpose of the currently proposed study is to provide the Agency with an initial understanding of potential consumer reactions to added sugars declarations on Nutrition Facts labels, information that would, in turn, help guide education efforts. In response to comments that raised concerns about the potential for added sugars declarations to affect consumer attention to and perceptions of other nutritional attributes presented in Nutrition Facts labels, FDA notes that the proposed experimental design is intended to address this possibility through the collection of respondent judgments of the nutritional attributes and overall healthfulness of foods that contain varying levels of calories, fat, and other nutrients. Additionally, as previously noted, FDA recognizes the importance of evaluating the potential effects of any proposed Nutrition Facts label modifications on consumer understanding. The proposed study will therefore include systematically varied experimental conditions and controls, and will employ appropriate measures to assess how various format modifications may affect consumer understanding of the Nutrition Facts label information. Due to resource limitations, the study cannot accommodate additional experimental conditions to evaluate consumer responses to ingredient listings. The study will, however, collect information about what names of various types of added sugars respondents recognize that might appear in ingredient listings.

(Comment 9) One comment objected to asking consumers about health effects (e.g., heart disease and diabetes) that consumers would associate with consuming a particular food product. The comment argued that consumer research questions should align with FDA's regulations regarding health claims, regulations which preclude suggestions that food substances may prevent, treat, or cure any particular disease or condition.

(Response 9) FDA disagrees with these comments. Several health conditions have been linked to dietary quality, and dietary quality is influenced by consumer perceptions and food choices. Regardless of FDA's regulations, consumers often make their own inferences about the relationships between food substances and the risk of various health conditions from labeling information. Rigorous and informative consumer research that aims to assess consumer understanding of labeling information typically accounts for the broader inferences consumers may make about food products, although the particular health conditions of interest in a particular consumer research study may vary (as evident in Refs. 1 to 3 and 15 to 24). In order to assess the extent to which consumers may infer broader health outcomes from nutrition information on the label, the study will ask respondents to judge whether people concerned about conditions such as osteoporosis or cancer should include a particular food item in their diet.

(Comment 10) One comment suggested that, instead of asking respondents if they use Nutrition Facts labels "To see if something said in advertising or on the package is actually true," the item be reworded to say "To confirm a statement in advertising or on the package," arguing that the former implies that inconsistency may exist between advertising and labeling statements and that consumers can independently verify label declarations.

(Response 10) The comment did not provide any data to support this rationale, and the Agency is not aware of any evidence to suggest that consumers interpret the survey item in question in the manner described in the comment. Nevertheless, this comment is no longer applicable to the proposed study because the item in question has been removed in order to prioritize collection of other information that is considered more relevant to the objectives of the current study.

(Comment 11) One comment stated that if the Agency is intending to include added sugars information on the Nutrition Facts label by indenting the phrase "Added Sugars" below where the declaration for "Sugars" appears, it is possible that consumers may not understand that added sugars are a subset of the amount of sugars. The comment suggested that the Agency study consumer responses to a Nutrition Facts format that adds the word "total" to the sugars declaration, so that this alternative format can also be evaluated in the proposed consumer research, noting that it might be beneficial to test more than one added sugars declaration format.

(Response 11) The Agency agrees with this comment and will plan to include an alternative label format that adds the word "total" to the sugars declaration in the proposed research. Thus, the study will include two formats for declaring "Added Sugars" on the Nutrition Facts label: one format in which the declaration is indented below a "Sugars" declaration, and one format in which the declaration is indented below a "Total Sugars" declaration.

(Comment 12) One comment suggested that the Agency use the cognitive interviews to ask consumers their understanding of the phrase "added sugars" as it appears on some of the experimental Nutrition Facts formats. The comment also recommended that the

number of cognitive interviews be sufficient to assess the level of comprehension of this terminology.

(Response 12) The Agency plans to conduct in-person cognitive interviews with participants of various ages, educational levels, and household incomes. The Agency agrees that it may be useful to ask cognitive interview participants about their understanding of the phrase "added sugars" and will include questions about this topic in all of the cognitive interviews that are conducted for the proposed study. Given that the primary purpose of the cognitive interviews is to assist with refinement of the questionnaire, the Agency does not agree that the number of cognitive interviews should be modified for assessing comprehension of added sugars terminology.

(Comment 13) One comment suggested that the proposed sample size for the study might be larger than necessary, unless the Agency expects to conduct subgroup analyses within experimental conditions.

(Response 13) As the comment noted, the Agency confirms that allowing for subgroup analyses constitutes one of the reasons for the proposed sample size. Another reason for the proposed sample size is to allow for assessment of interactions between the various experimental factors (e.g., label format × food category × nutrition profile). Indeed, the ability to detect interactions is of equal, if not more, importance to fulfilling the Agency's information objectives than the ability to detect only the main effects of experimental factors such as label format, food category, or nutrition profile.

(Comment 14) One comment suggested two alternative definitions for percent Daily Value: a) "The Percent Daily Value tells you how much of a day's worth of a nutrient one serving of this food provides"; and b) "The Percent Daily Value tells you how much of a day's worth of a nutrient you would get from one serving of this food."

(Response 14) Due to resource limitations, the Agency is not able to test the alternative definitions of percent Daily Value suggested in this comment.

(Comment 15) One comment objected to asking respondents to evaluate whether a product is an "excellent source" of or "low" in a particular nutrient relative to footnote messages that indicate that 5% or less of the Daily Value for a nutrient is "low" or "a little" and 20% or more of the Daily Value is "high" or "a lot." The comment raised concerns that consumers may not interpret or apply such footnote messages as FDA intends.

(Response 15) FDA agrees that some consumers may not interpret or apply a particular footnote message as FDA intends. That is one reason for asking respondents to characterize the vitamin and nutrient content of selected products. Collecting information about differences between consumer interpretations of information versus FDA definitions will help guide FDA's ongoing informational efforts to provide consumer guidance on how to use percent Daily Values.

(Comment 16) Two comments suggested that FDA test effects of including "high" and "low" text next to the appropriate nutrients on the NF label in accordance with the 5% and 20% guideline levels. One of these comments also suggested certain nutrients and their amounts be printed in red ink or against a red background, in conjunction with the word "high" being printed in red and positioned between the amount of the nutrient and the percent Daily Value.

(Response 16) The Agency has studied the use of adjectives such as "high" and "low" on Nutrition Facts labels in prior research (Refs. 1 and 3). That research found that Nutrition Facts formats that included adjectives did not significantly improve respondents' accuracy in dietary judgment tasks relative to Nutrition Facts formats that did not include such adjectives. Specifying a particular color scheme for selected content in the Nutrition Facts label or adding amount descriptors next to certain nutrients are beyond the scope of this study.

(Comment 17) One comment suggested testing alternative statements for recommended caloric intake, including statements of calorie ranges; statements indicating that calorie requirements change with age, height, and activity level; and statements suggesting consumers check their own caloric needs on a government run website (e.g., www.choosemyplate.gov). A proposed sample statement offered was: "The recommended daily intake for an average adult is 2,000 calories. See www.xxx.gov for individual calorie needs based on gender, age and activity level."

(Response 17) Due to resource limitations, the Agency is not able to test the alternative statements for recommended caloric intake suggested in this comment. In addition to calorie requirements changing with age, height, and activity level, as the comment stated, calorie requirements also vary according to a number of other factors, including body composition (percentages of lean body mass and body fat), basal and resting metabolic rate, ambient temperature, genetic factors, whether a woman is pregnant or lactating, and others. An accurate label statement explaining how calorie needs vary would be too lengthy and complex for inclusion on Nutrition Facts labels. Using the phrase "recommended daily intake" for calorie requirements, as the comment suggests, could also be problematic, since 2,000 calories is not a recommended intake level, but is rather used as the basis for setting Daily Reference Values (DRVs) for nutrients having DRVs that are based on caloric intake. Finally, there are many websites that provide information on estimating individual calorie needs. The question of whether it would be suitable for the Nutrition Facts label to single out any one particular website is beyond the scope of the study.

9. Explanation of Any Payment or Gift to Respondents

Cognitive interview participants will be recruited from a commercial database of residents in the Washington, D.C. metropolitan area. As an incentive, each respondent will be offered $40 to participate in the one-hour interview.

Study respondents will be recruited from members of the contractor's consumer panel. Members have voluntarily agreed to join the panel and participate in regular online

surveys conducted by Ipsos. Ipsos offers panelists two main incentive programs: sweepstakes draws and a point system. The sweepstakes draw is conducted quarterly. One prize consisting of $5,000 USD is available to be won for each drawing, and the odds of winning depend upon the number of eligible entries each quarter. Panel members receive an entry into the draw for each sweepstake-based survey they complete during this time period. Smaller sweepstakes (less than $1000 USD) are also offered periodically depending on the market. In the points program, panelists earn points for each survey based on survey length, and receive additional bonus points on a sliding scale for completing a certain number of surveys (e.g., 5 surveys = 25 points and 25 surveys = 100 points). Points can be redeemed for cash, prepaid cards, and charitable donations.

The use of incentives is a standard practice in data collection in general (see the American Association of Public Opinion Research Best Practices Guidelines at http://www.aapor.org/Best_Practices1.htm#best9). To ensure adequate participation and high data quality, and to help ensure that participants are reasonably diverse in age, gender, and education, we propose the above incentive amounts. These amounts were determined based on information provided by our contractors about the going rates offered to participants at various locations across the country for consumer research of similar type, scope, and length of time. The incentive amount for cognitive interviews also reflects the current cost of gas and other travel expenses.

10. Assurance of Confidentiality Provided to Respondents

All data will be collected with an assurance that the respondents' answers will remain confidential. The study instrument will contain a statement that responses will be kept confidential. Identifying information will not be included in the data files delivered by contractors to the Agency. Information will be kept private to the extent permitted by law.

Confidentiality will be assured by using an independent contractor, Ipsos, to collect the information, by enacting procedures to prevent unauthorized access to respondent data, and by preventing the public disclosure of the responses of individual participants. The contractor will only share data and/or information with the Agency in an aggregated form or format, which does not permit the Agency to identify individual respondents. Ipsos will not share personal information with a third party unless it requests and is granted the panelists' permission to pass on the information. Details of the Ipsos privacy policy can be found at http://www.ipsos-na.com/privacy/.

All electronic data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in accordance with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

11. Justification for Sensitive Questions

The survey does not include any questions that are of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

To help design and refine the questionnaire, FDA plans to conduct cognitive interviews by screening 72 panelists in order to obtain 9 participants in the interviews. Each screening is expected to take 5 minutes (0.083 hour) and each cognitive interview is expected to take one hour. The total for cognitive interview activities is 15 hours (6 hours + 9 hours). Subsequently, we plan to conduct pretests of the questionnaire before it is administered in the study. We expect that 1,000 invitations, each taking 2 minutes (0.033 hours), will need to be sent to adult members of an online consumer panel to have 150 of them complete a 15-minute (0.25 hours) pretest. The total for the pretest activities is 71 hours (33 hours + 38 hours). For the survey, we estimate that 40,000 invitations, each taking 2 minutes (0.033 hours), will need to be sent to adult members of an online consumer panel to have 10,000 of them complete a 15-minute (0.25 hours) questionnaire. The total for the survey activities is 3,820 hours (1,320 hours + 2,500 hours). Thus, the total estimated burden is 3,906 hours.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive interview screener	72	1	72	0.083 (5 min.)	6
Cognitive interview	9	1	9	1	9
Pretest invitation	1,000	1	1,000	0.033 (2 min.)	33
Pretest	150	1	150	0.25 (15 min.)	38
Survey invitation	40,000	1	40,000	0.033 (2 min.)	1,320
Survey	10,000	1	10,000	0.25 (15 min.)	2,500
Total					3,906

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $66,402 (3906 x 17) at $17 per hour (the 2012 median wage rate in the U.S., rounded to the nearest dollar).[1]

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

[1] http://www.bls.gov/oes/current/oes_nat.htm, accessed April 2013.

The estimated total cost to the Federal Government for this information collection is $200,000. This includes the value of the task order to develop and conduct the collection of information and the value of a Full-Time-Employee to develop, monitor and analyze the data collection.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The Agency will use the study results to help inform proposed regulations for the modification of Nutrition Fact label on food products. The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. Final results of the study may be summarized for publication in a peer-reviewed scientific journal. The planned schedule for project activities is shown in Table 2.

Table 2. -- Project Schedule

Date	**Activity**	**Audience**
Within 3 days after receipt of OMB approval of collection of information	Notification to the contractor to proceed with data collection activities	Not applicable
Within 135 days after notification to contractor	Completion of data collection	Not applicable
Within 180 days after notification to contractor	Delivery by the contractor of final data files	Not applicable
Within 6 months after receipt of final data files	Delivery of oral and written preliminary summaries	FDA
Within 18 months after receipt of final data files	Delivery of a written final report of summaries and analytical findings	FDA
Within 18 months after receipt of final data files	Response to information requests	FDA and public
Within 24 months after receipt of final data files	Submission of manuscript(s) of journal article(s) to disseminate information and analytical findings	Public

FDA will disseminate the results of this study strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public." In describing the data collected and results of the analysis, FDA will clearly acknowledge that the research is not intended or to be used for developing nationally representative population estimates of consumer attitudes, knowledge, or behaviors and that the research provides valid and quantitative estimates of differences across experimental conditions.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB approval and expiration date will be displayed on all materials associated with the study.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References:

1. Levy, A.S., Fein, S.B., and Schucker, R.E. "Nutrition Labeling Formats: Performance and Preference," Food Technology, 45: 116-121, 1991.
2. Levy, A.S., S.B. Fein, and R.E. Schucker, "More effective nutrition label formats are not necessarily preferred," Journal of the American Dietetic Association, vol. 92, pp. 1230-1234, 1992.
3. Levy, A.S., Fein, S.B., and Schucker, R.E. "Performance Characteristics of Seven Nutrition Label Formats," Journal of Public Policy and Marketing, 15: 1-15, 1996.
4. U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2010. 7th Edition, Washington, DC: U.S. Government Printing Office, December 2010.
5. Institute of Medicine. "Executive Summary, Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride," Washington, DC: National Academy Press, pp. 1-20, 1997.
6. Institute of Medicine. "Executive Summary, Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline," Washington, DC: National Academy Press, pp. 1-16, 1998.
7. Institute of Medicine. "Executive Summary, Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids," Washington, DC: National Academy Press, pp. 1-20, 2000.
8. Institute of Medicine. "Executive Summary, Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc," Washington, DC: National Academy Press, pp. 1-28, 2001.
9. Institute of Medicine. Dietary Reference Intakes: Proposed Definition of Dietary Fiber, Washington, DC: National Academy Press, 2001.
10. Institute of Medicine. "Executive Summary, Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids," Washington, DC: National Academies Press, pp. 1-19, 2002.
11. Institute of Medicine. "Executive Summary, Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate," Washington, DC: National Academies Press, pp. 1-20, 2004.
12. U.S. Food and Drug Administration. "2008 Health and Diet Survey – Preliminary Topline Frequencies (Weighted)," 2010, available at

http://www.fda.gov/Food/ScienceResearch/ResearchAreas/ConsumerResearch/ucm193895.htm

13. Li, F., Miniard, P.W., and Barone, M.J. "The Facilitating Influence of Consumer Knowledge on the Effectiveness of Daily Value Reference Information," Journal of the Academy of Marketing Science, 28: 425-436, 2000.

14. Levy, L., Patterson, R.E., Kristal, A.R., and Li, S.S. "How Well Do Consumers Understand Percentage Daily Value on Food Labels?" American Journal of Health Promotion, 14: 157-160, 2000.

15. U.S. Food and Drug Administration, "A Key to Choosing Healthful Foods: Using the Nutrition Facts on the Food Label," available at http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079449.htm

16. U.S. Food and Drug Administration, "The Food Label and You - Video," available at http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm275409.htm

17. U.S. Food and Drug Administration, "How to Understand and Use the Nutrition Facts Label," available at http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm274593.htm

18. U.S. Food and Drug Administration, "Using the Nutrition Facts Label. A How-to Guide for Older Adults," available at http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm267499.htm

19. U.S. Food and Drug Administration, "Spot The Block Campaign For Tweens," available at http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm281757.htm

20. U.S. Food and Drug Administration. "Spot the Block: Get Your Food Facts First," available at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048815.htm

21. Andrews, J.C., S. Burton, and R.G. Netemeyer, "Are some comparative nutrition claims misleading? The role of nutrition knowledge, ad claim type and disclosure conditions," Journal of Advertising, vol. 29, pp. 29-42, 2000.

22. Barone, M.J., R.L. Rose, K.C. Manning, and P.W. Miniard, "Another look at the impact of reference information on consumer impressions of nutrition information," Journal of Public Policy & Marketing, vol. 15, pp. 55-62, 1996.

23. Burton, S., J.A. Garretson, and A.M. Velliquette, "Implications of accurate usage of Nutrition Facts panel information for food product evaluations and purchase intentions," Journal of the Academy of Marketing Science, vol. 27, pp. 470-480, 1999.

24. Crites, S.L. and S.N. Aikman, "Impact of nutrition knowledge on food evaluations," European Journal of Clinical Nutrition, vol. 59, pp. 1191-1200, 2005.

25. Ford, G.T., M. Hastak, A. Mitra, and D.J. Ringold, “Can consumers interpret nutrition information in the presence of a health claim? A laboratory investigation,” Journal of Public Policy & Marketing, vol. 15, pp. 16-27, 1996.

26. Howlett, E., S. Burton, and J. Kozup, “How modification of the Nutrition Facts panel influences consumers at risk for heart disease: the case of trans fat,” Journal of Public Policy & Marketing, vol. 27, pp. 83-97, 2008.

27. Lando, A.M. and S.C. Lo, “Single-larger-portion-size and dual-column nutrition labeling may help consumers make more healthful food choices,” Journal of the Academy of Nutrition and Dietetics, vol. 113, pp. 241-250, 2013.

28. Roberto, C.A., M.A. Bragg, M.J. Seamans, R.L. Mechulan, N. Novak, and K.D. Brownell, “Evaluation of consumer understanding of different front-of-package nutrition labels, 2010-2011,” Preventing Chronic Disease, vol. 9, 120015. DOI: http://dx.doi.org/10.5888/pcd9.120015, 2012a.

29. Roberto, C.A., M.A. Bragg, M.B. Schwartz, M.J. Seamans, A. Musicus, N. Novak, and K.D. Brownell, “Facts Up Front versus traffic light food labels. A randomized controlled trial,” American Journal of Preventive Medicine, vol. 43, pp. 134-141, 2012b.

30. Roe, B., AS. Levy, and B.M. Derby, “The impact of health claims on consumer search and product evaluation outcomes: results from FDA experimental data,” Journal of Public Policy & Marketing, vol. 18, pp. 89-105, 1999.

31. Chandon, P. How package design and package-based marketing claims lead to overeating. Applied Economic Perspectives and Policy, vol. 35, pp. 123-147, 2013.

32. Chandon P. and B. Wansink, “Does food marketing need to make us fat? A review and solutions,” Nutrition Reviews, vol. 70, pp. 571-593, 2012.